

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL INDUSTRY	)	
AVERAGE WHOLESALE PRICE	)	MDL No. 1456
LITIGATION	)	
	)	
	)	CIVIL ACTION: 01-CV-12257 PBS
THIS DOCUMENT RELATES TO:	)	
	)	
<i>State of Iowa v. Abbott Laboratories, et al.</i>	)	Judge Patti B. Saris
	)	
	)	

**ANSWER AND AFFIRMATIVE DEFENSES OF BOEHRINGER INGELHEIM  
ROXANE, INC. TO THE STATE OF IOWA'S COMPLAINT**

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Defendant Boehringer Ingelheim Roxane, Inc., f/k/a Roxane Laboratories, Inc. (“Roxane”) hereby states as its Answer and Affirmative Defenses to the State of Iowa’s Complaint, dated October 9, 2007, as follows:

**PRELIMINARY STATEMENT**

The State of Iowa’s Complaint (the “Complaint”) improperly refers to Roxane, other Defendants, and third parties on a collective basis, failing to plead with requisite particularity allegations against Roxane. This is insufficient to apprise Roxane of the allegations asserted against it. Roxane has nevertheless attempted to respond to Plaintiff’s allegations to the extent possible.

To the extent the allegations in the Complaint refer to the knowledge, conduct or actions of other persons or entities, Roxane generally lacks knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore denies them. Roxane states that it is answering Plaintiff’s allegations solely on behalf of itself, even when Roxane’s allegations refer to alleged conduct by Roxane and other persons or entities.

The Complaint also contains purported quotations from a number of sources. In answering allegations consisting of quotations, Roxane’s failure to deny that the material quoted was contained in a document or was uttered by the person or entity quoted or Roxane’s reference to the full document instead of the quote shall not constitute an admission that the substantive content of the quote or document is or is not true or that the material is relevant or admissible in this action.

Roxane denies each and every allegation contained in the Complaint and the exhibits thereto, except as specifically herein admitted, and any factual averment admitted herein is admitted only as to the specific facts and not as to any conclusions, characterizations, implications, innuendos or speculation contained in any particular averment or in the Complaint as a whole. In addition, Roxane specifically denies any allegations contained in headings, footnotes, or unnumbered paragraphs in the Complaint. For ease of reference, Roxane has included in this Answer and Affirmative Defenses certain captions used in the Complaint, but specifically denies any allegations contained in, or inferences that could be drawn from, those captions.

These comments and objections are incorporated, to the extent appropriate, into each unnumbered and numbered paragraph of this Answer.

### **SPECIFIC RESPONSES**

1. Roxane admits that the State of Iowa (the “State”) seeks to bring this action as alleged in Paragraph 1 of the Complaint, but Roxane denies that there is any basis for the State to do so and denies that the State is entitled to any relief.

2. To the extent the allegations in Paragraph 2 are directed at Roxane, Roxane denies them. Roxane specifically denies that it “purposefully report[s] false and inflated price information.” To the extent the allegations in Paragraph 2 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

Paragraphs 3 through 4. To the extent the allegations in Paragraphs 3-4 are directed at Roxane, Roxane denies them. Roxane specifically denies that it submits

“false and inflated pricing information in order to ‘create a spread.’” Roxane further denies the characterization of “spread” in Paragraphs 3-4. To the extent the allegations in Paragraphs 3-4 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

5. Roxane lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 5, and therefore denies these allegations.

6. To the extent the allegations in Paragraph 6 are directed at Roxane, Roxane denies them. Roxane specifically denies that it “purposefully manipulate[s] a market that, by defendants’ own design, is extremely complicated and non-transparent.” To the extent the allegations in Paragraph 6 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

Paragraphs 7 through 8. Roxane lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 7-8, and therefore denies these allegations.

9. To the extent the allegations in Paragraph 9 are directed at Roxane, Roxane denies them. Roxane specifically denies that it engages in any “unlawful price reporting activity [that] infects all four [pricing] benchmarks and renders each of them false and inflated.” To the extent the allegations in Paragraph 9 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

10. Roxane lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 10, and therefore denies these allegations, except it admits that it pays Medicaid rebates to Iowa. To the extent the allegations in Paragraph 10 or its footnote refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

11. To the extent the allegations in Paragraph 11 are directed at Roxane, Roxane denies them. Roxane specifically denies that it does not accurately report Best Prices. To the extent the allegations in Paragraph 11 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

12. To the extent the allegations in Paragraph 12 are directed at Roxane, Roxane denies them. Roxane specifically denies that it engages in “unlawful pricing schemes,” the “manipulation of the Medicaid program” or the “improper reporting of false and inflated pricing information” resulting in “overcharges . . . to the Iowa Medicaid Program.” To the extent the allegations in Paragraph 12 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

13. To the extent the allegations in Paragraph 13 are directed at Roxane, Roxane denies them. Roxane specifically denies that it engages in “wrongful practices” that have a “pernicious . . . effect on the public fisc.” To the extent the allegations in Paragraph 13 are directed at parties other than Roxane, Roxane lacks knowledge or

information sufficient to form a belief as to their truth, and therefore denies these allegations.

Paragraphs 14 through 15. Roxane admits that it voluntarily participates in the Iowa Medicaid program, but denies that it has violated any State or Federal law. To the extent the allegations in Paragraphs 14-15 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations. To the extent the allegations in Paragraphs 14-15 refer to judicial opinions, those sources speak for themselves, and any characterizations thereof are denied.

16. To the extent the allegations in Paragraph 16 are directed at Roxane, Roxane denies them. Roxane specifically denies that it “intentionally report[s] false prices to the government.” To the extent the allegations in Paragraph 16 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

17. To the extent the allegations in Paragraph 17 are directed at Roxane, Roxane denies them. Roxane specifically denies that it engages in “fraudulent, unfair and deceptive practices.” To the extent the allegations in Paragraph 17 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

18. Roxane admits that Exhibit B to the Complaint purports to identify the prescription drugs at issue in this matter, but denies any liability to Plaintiff with respect to any such NDCs. To the extent the allegations in Paragraph 18 are directed at parties

other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

19. Roxane lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 19, and therefore denies these allegations. To the extent the allegations in Paragraph 19 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

20. To the extent that the allegations in Paragraph 20 are directed at Roxane, Roxane denies them, except Roxane admits that it manufactures and sells prescription drugs and that it participates in the Iowa Medicaid Program. To the extent the allegations in Paragraph 20 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

21. Roxane admits that it conducts business in the State of Iowa.

Paragraphs 22 through 29. The allegations in Paragraphs 22-29 are directed to other Defendants and require no response from Roxane. To the extent a response is deemed to be required, Roxane lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 22-29, and therefore denies these allegations.

30. With respect to the allegations in Paragraphs 30 (a)-(d), Roxane admits that Boehringer is a Nevada corporation with its principal place of business located at 900 Ridgebury Rd., Ridgefield, CT 06877, that Boehringer is a subsidiary of Pharma Investment Limited of Burlington, Canada ("Pharma") and that C.H. Boehringer Sonn

Grundstücksverwaltung GmbH & Co. KG (“C.H. Boehringer”) is a German corporation located in Ingelheim, Germany. Roxane denies the remaining allegations that pertain to Pharma and C.H. Boehringer. Roxane admits that Roxane is a Delaware corporation engaged in the business of manufacturing pharmaceuticals, with its principal place of business located at 1809 Wilson Road, Columbus, OH 43216-6532. Roxane admits that it is a wholly-owned subsidiary of Boehringer. Roxane denies, for the time period April, 2005 to the present, that Roxane is engaged in the business of selling pharmaceuticals. Roxane further admits that BIPI is a wholly-owned subsidiary of Boehringer, and that it is engaged in the business of manufacturing and selling pharmaceuticals. Roxane admits that BIPI’s principal place of business is located at 900 Ridgebury Rd., Ridgefield, CT 06877, but denies that BIPI is a Connecticut corporation. Roxane admits that Ben Venue is a Delaware corporate engaged in the business of manufacturing and selling pharmaceuticals, with its principal place of business located at 300 Northfield Road, Bedford, OH 44146. Roxane admits that Ben Venue was acquired by Boehringer in 1997. Roxane further admits that Bedford Laboratories (“Bedford”) is a division of Ben Venue that was created in or about 1993. Roxane admits that Roxane, BIPI, and Ben Venue are subsidiaries of Boehringer. Roxane affirmatively avers that reference to Roxane, BIPI and Ben Venue, three separate corporate entities, as the “Boehringer Group” is inappropriate and improper. Roxane lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 30 and its sub-parts, and therefore denies these allegations.

Paragraphs 31 through 58. The allegations in Paragraphs 31-58 are directed to other Defendants and require no response from Roxane. To the extent a response is



deemed to be required, Roxane lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 31-58, and therefore denies these allegations.

59. Roxane admits that the State seeks to bring this action as alleged in Paragraph 59, but Roxane denies there is any basis for the State to do so and denies that the State is entitled to any relief.

Paragraphs 60 through 61. Paragraphs 60-61 state legal conclusions as to which no response is required. To the extent a response is deemed to be required, Roxane denies the allegations in Paragraphs 60-61, and notes that this captioned matter has been transferred to this Court by the Judicial Panel on Multi District Litigation, pursuant to 28 U.S.C. § 1407.

62. With respect to the allegations in Paragraph 62, Roxane admits that Medicaid was established by Title XIX of the Social Security Act. Roxane further states that the provisions of Title XIX speak for themselves, and any characterizations thereof are denied.

63. Roxane lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 63, and therefore denies these allegations, except Roxane admits that state participation in Medicaid is voluntary and that state Medicaid plans must be approved by the federal government. To the extent the allegations in Paragraph 63 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

Paragraphs 64 through 65. Roxane lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 64-65, and therefore denies these allegations. To the extent the allegations in Paragraphs 64-65 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

66. Roxane lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 66, and therefore denies these allegations, except admits that national drug codes are assigned to prescription drugs.

67. To the extent the allegations in Paragraph 67 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. Roxane otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 67, and therefore denies these allegations.

68. Roxane lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 68, and therefore denies these allegations. To the extent the allegations in Paragraph 68 refer to an OIG report, the report speaks for itself, and any characterizations thereof are denied.

69. Roxane lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 69, and therefore denies these allegations. To the extent the allegations in Paragraph 69 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

70. Roxane lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 70, and therefore denies these allegations.

Paragraphs 71 through 72. To the extent the allegations in Paragraphs 71-72 are directed at Roxane, Roxane denies them. Roxane further states that for years, and at all times relevant to the Complaint, it has been common knowledge and universally understood, including by the State and/or its agents, that AWP does not, and is not intended to, reflect an actual average of wholesale prices. To the extent the allegations in Paragraphs 71-72 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

Paragraphs 73 through 80. Roxane lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 73-80 or their subsections, and therefore denies these allegations. To the extent the allegations in Paragraphs 73-80 or their subsections refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

81. Roxane lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 81, except that it admits that pricing compendia such as First DataBank and Medi-Span publish AWP's and FULs, and denies that Roxane has any control over such prices.

82. To the extent the allegations in Paragraph 82 are directed at Roxane, Roxane denies them. Roxane specifically denies that it "purposefully and fraudulently conceal[s]" the "true prices" of its drugs by "claiming they are proprietary trade secrets."

To the extent the allegations in Paragraph 82 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

83. Roxane lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 83, and therefore denies these allegations.

84. To the extent the allegations in Paragraph 84 are directed at Roxane, Roxane denies them. Roxane specifically denies that it “fraudulently misrepresent[s]” its true prices or that it reports “false and inflated prices.” To the extent the allegations in Paragraph 84 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

85. To the extent the allegations in Paragraph 85 are directed at Roxane, Roxane denies them, except that Roxane admits that Exhibit A purports to identify total expenditures by Defendant. Roxane specifically denies any “unfair practices, deception, and fraud.” To the extent the allegations in Paragraph 85 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

86. To the extent the allegations in Paragraph 86 are directed at Roxane, Roxane denies them. Roxane specifically denies conducting any “fraudulent practices.” To the extent the allegations in Paragraph 86 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

Paragraphs 87 through 89. To the extent the allegations in Paragraphs 87-89 are directed at Roxane, Roxane denies them. Roxane specifically denies that it reports “false and inflated” “WACs or WAC equivalents.” To the extent the allegations in Paragraphs 87-89 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

Paragraphs 90 through 92. To the extent the allegations in Paragraphs 90-92 are directed at Roxane, Roxane denies them. Roxane further states that these allegations wrongly assume that discounts, chargebacks and other price concessions are supposed to be included in prices reported to industry compendia. To the extent the allegations in Paragraphs 90-92 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

Paragraphs 93 through 98. To the extent the allegations in Paragraphs 93-98 are directed at Roxane, Roxane denies them, except Roxane admits that it has at times identified an AWP or WAC for certain of its drugs. Roxane further admits that it has at times provided AWP or WAC for some of its drugs to certain pharmaceutical industry compendia and that publishers apply their own markups to the list prices. Roxane specifically denies that it “either report[s] or caused to be reported false and inflated AWPs,” “false WAC or WAC equivalents,” or that Roxane “alone control[s] the false and inflated AWPs that are published for [its] drugs.” Roxane further states that for years, and at all times relevant to the Complaint, it has been common knowledge and universally understood, including by the State and/or its agents, that AWP does not, and is not intended to, reflect an actual average of wholesale prices. To the extent the

allegations in Paragraphs 93-98 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

99. Roxane lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 99, and therefore denies these allegations.

100. To the extent the allegations in Paragraph 100 are directed at Roxane, Roxane denies them. To the extent the allegations in Paragraph 100 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

101. To the extent the allegations in Paragraph 101 or the exhibit referenced therein are directed at Roxane, Roxane denies them. To the extent the allegations in Paragraph 101 or the exhibit referenced therein are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

Paragraphs 102 through 108. The allegations in Paragraphs 102-108 require no response from Roxane on the grounds that Exhibit B does not name any Roxane drugs subject to the FUL. To the extent the allegations in Paragraphs 102-108 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

109. The allegations in Paragraph 109 require no response from Roxane on the grounds that the Iowa SMAC claims have been dismissed by the Court.

Paragraphs 110 through 128. To the extent the allegations in Paragraphs 110-128 are directed at Roxane, Roxane denies them, except Roxane admits that it has executed a rebate agreement with HHS. The rebate agreement speaks for itself, and any characterizations thereof are denied. To the extent the allegations in Paragraphs 110-128 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denied these allegations. To the extent the allegations in Paragraphs 110-128 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

Paragraphs 129 through 132. To the extent the allegations in Paragraphs 129-132 are directed at Roxane, Roxane denies them, and further states that the Court has dismissed all Medicaid rebate-related allegations in the Complaint as to Roxane. To the extent the allegations in Paragraphs 129-132 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations. To the extent the allegations in Paragraphs 129-132 refer to statutes, regulations or reports, those sources speak for themselves, and any characterizations thereof are denied.

133. To the extent the allegations in Paragraph 133 are directed at Roxane, Roxane denies them. Roxane specifically denies that it has participated in any “pricing scheme . . . by exacerbating the complexities of the . . . drug market.” To the extent the allegations in Paragraph 133 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

134. To the extent the allegations in Paragraph 134 are directed at Roxane, Roxane denies them. Roxane specifically denies that it “purposefully conceal[s its] true prices.” To the extent the allegations in Paragraph 134 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations. To the extent the allegations in Paragraph 134 refer to the transcript of a congressional hearing, the transcript speaks for itself, and any characterizations thereof are denied.

135. To the extent the allegations in Paragraph 135 are directed at Roxane, they are denied. To the extent the allegations in Paragraph 135 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

136. To the extent the allegations in Paragraph 136 are directed at Roxane, they are denied, except Roxane admits that certain of its contracts are subject to confidentiality agreements and that Roxane does offer discounts to certain of its customers. To the extent the allegations in Paragraph 136 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

137. To the extent the allegations in Paragraph 137 are directed at Roxane, Roxane denies them. Roxane specifically denies that it “obscure[s] the true prices for [its] drugs with [its] policy of treating different classes of trade differently.” To the extent the allegations in Paragraph 137 are directed at parties other than Roxane, Roxane



lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

Paragraphs 138 through 139. To the extent the allegations in Paragraphs 138-139 are directed at Roxane, Roxane denies them. Roxane specifically denies that it “maintain[s] two sets of pricing records: one with [] inflated prices and another with [] actual prices.” To the extent the allegations in Paragraphs 138-139 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations. To the extent the allegations in Paragraphs 138-139 refer to the transcript of a congressional hearing, the transcript speaks for itself, and any characterizations thereof are denied.

Paragraphs 140 through 141. To the extent the allegations in Paragraphs 140-141 are directed at Roxane, Roxane denies them. Roxane specifically denies that it “hide[s] its] real drugs prices by secretly providing free drugs and phony grants” or that it conceals its true prices “to create spreads between actual cost and reimbursement amounts . . . to influence market share.” To the extent the allegations in Paragraphs 140-141 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

142. To the extent the allegations in Paragraph 142 are directed at Roxane, Roxane denies them. To the extent the allegations in Paragraph 142 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

143. To the extent the allegations in Paragraph 143 are directed at Roxane, Roxane denies them. Roxane further states that for years, and at all times relevant to the Complaint, it has been common knowledge and universally understood, including by the State and/or its agents, that AWP does not, and is not intended to, reflect an actual average of wholesale prices. To the extent the allegations in Paragraph 143 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

Paragraphs 144 through 145. To the extent the allegations in Paragraphs 144-145 are directed at Roxane, Roxane denies them, except it admits that it has at times identified an AWP or WAC for certain of its drugs. Roxane further admits that it has at times provided AWP or WAC for some of its drugs to certain pharmaceutical industry compendia. Roxane specifically denies that it has engaged in any “unlawful and undisclosed manipulation of the price reporting system” or caused the “publication of a false WAC,” AWP, or FUL. To the extent the allegations in Paragraphs 144-145 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

146. To the extent the allegations in Paragraph 146 are directed at Roxane, Roxane denies them. Roxane specifically denies that it has “caus[ed] false prices to be published.” To the extent the allegations in Paragraph 146 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

147. To the extent the allegations in Paragraph 147 are directed at Roxane, Roxane denies them. Roxane specifically denies that it “submit[s] false and inflated wholesale price information in order to create a spread.” Roxane further denies the characterization of “spread” in Paragraph 147. To the extent the allegations in Paragraph 147 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

148. To the extent the allegations in Paragraph 148 are directed at Roxane, Roxane denies them. Roxane specifically denies that it has “corrupted the market for prescription drugs” or has “deliberately sought to create a powerful financial incentive for providers to prescribe drugs based primarily on the spread.” Roxane further denies the characterization of “spread” in Paragraph 148. To the extent the allegations in Paragraph 148 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

Paragraphs 149 through 150. To the extent the allegations in Paragraphs 149-150 are directed at Roxane, Roxane denies them. Roxane specifically denies that it “market[s] its] products based on the spread between reimbursement (based on AWP, WAC, or a WAC equivalent) and actual acquisition cost” or that it “compete[s] on reimbursement and profit rather than cost.” To the extent the allegations in Paragraphs 149-150 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

Paragraphs 151 through 152. To the extent the allegations in Paragraphs 151-152 are directed at Roxane, Roxane denies them. To the extent the allegations in Paragraphs

151-152 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations. To the extent the allegations in Paragraphs 151-152 refer to the transcript of a congressional hearing, the transcript speaks for itself, and any characterizations thereof are denied.

Paragraphs 153 through 154. To the extent the allegations in Paragraphs 153-154 are directed at Roxane, Roxane denies them. Roxane specifically denies that it has “intentionally manipulat[ed] the nation’s drug reimbursement system . . . with false and inflated prices.” To the extent the allegations in Paragraphs 153-154 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

Paragraphs 155 through 157. To the extent the allegations in Paragraphs 155-157 are directed at Roxane, Roxane denies them. Roxane specifically denies that it reports “reimbursement prices . . . to the publishing compendia” or that it engages in “purposeful AWP manipulation.” Roxane further states that for years, and at all times relevant to the Complaint, it has been common knowledge and universally understood, including by the State and/or its agents, that AWP does not, and is not intended to, reflect an actual average of wholesale prices. To the extent the allegations in Paragraphs 155-157 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations. To the extent the allegations in Paragraphs 155-157 refer to HHS OIG reports, the reports speak for themselves, and any characterizations thereof are denied.

158. To the extent the allegations in Paragraph 158 are directed at Roxane, Roxane denies them. Roxane specifically denies that it reports “price information that . . . does not comply with the HHS OIG’s guidelines” by not accounting for various types of discounts. To the extent the allegations in Paragraph 158 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

Paragraphs 159 through 165. Roxane lacks knowledge or information to form a belief as to the truth of the allegations in Paragraphs 159-165, except Roxane admits that it participates in the Federal Medicaid Rebate Program through which Iowa Medicaid is obligated to reimburse providers for Roxane drugs. Roxane further states that for years, and at all times relevant to the Complaint, it has been common knowledge and universally understood, including by the State and/or its agents, that AWP does not, and is not intended to, reflect an actual average of wholesale prices or have an expected relationship to such an average. To the extent the allegations in Paragraphs 159-165 refer to judicial opinions, those sources speak for themselves, and any characterizations thereof are denied.

166. To the extent the allegations in Paragraph 166 are directed at Roxane, Roxane denies them. To the extent the allegations in Paragraph 166 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

Paragraphs 167 through 171. To the extent that the allegations in Paragraphs 167-171 are directed at Roxane, Roxane denies them, except Roxane lacks knowledge or

information sufficient to form a belief as to the truth of the allegation that the “Iowa Medicaid Program spent over \$1.6 billion for defendants’ drugs between 1992 and 2005 alone.” Roxane specifically denies that it “knowingly interfered with Iowa’s ability to reimburse providers at EAC.” To the extent the allegations in Paragraphs 167-171 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

Paragraphs 172 through 177. With respect to the allegations in Paragraphs 172-177, Roxane admits that Exhibit B to the Complaint purports to identify the prescription drugs at issue in this matter, but denies the accuracy of the data listed therein. To the extent the remaining allegations in Paragraphs 172-177 or Exhibit B are directed at Roxane, Roxane denies them, except Roxane admits that it has at times identified an AWP or WAC for certain of its drugs. Roxane further admits that it has at times provided AWP or WAC for some of its drugs to certain pharmaceutical industry compendia. Roxane specifically denies that it “routinely submitted false prices” to pricing compendia. Roxane further denies the characterization of “spread” in Paragraphs 172-177 and Exhibit B. To the extent the allegations in Paragraphs 172-177 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

178. To the extent the allegations in Paragraph 178 are directed at Roxane, Roxane denies them. To the extent the allegations in Paragraph 178 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

179. To the extent the allegations in Paragraph 179 are directed at Roxane, Roxane denies them, except Roxane admits that its contracts with purchasers sometimes included discounts. To the extent the allegations in Paragraph 179 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

180. To the extent the allegations in Paragraph 180 or the exhibit referenced therein are directed at Roxane, Roxane denies them. To the extent the allegations in Paragraph 180 or the exhibit referenced therein are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

Paragraphs 181 through 298. The allegations in Paragraphs 181-298 are directed to other Defendants and require no response from Roxane. To the extent a response is deemed to be required, Roxane lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 181-298, and therefore denies these allegations.

299. Roxane lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 299 or its footnote or exhibit referenced therein, and therefore denies them, and specifically denies that it engaged in any “fraud.”

300. Roxane denies the allegations in Paragraph 300 and the exhibit referenced therein.

301. Roxane admits that it prepared a “worksheet” for internal purposes that illustrated spreads between AWP and acquisition cost. Roxane denies the remaining allegations in Paragraph 301.

302. Roxane admits it has offered its prescription drugs to its customers at prices below the published AWP and that it knew some customers cared about “spread.” Roxane denies that it “actively marketed and manipulated the spread” and denies the remaining allegations in Paragraph 302. Roxane further states that for years, and at all times relevant to the Complaint, it has been common knowledge and universally understood, including by the State of Iowa and/or its agents, that AWP does not, and is not intended to, reflect an actual average of wholesale prices.

303. Roxane lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 303, and therefore denies these allegations and the exhibit referenced therein. Roxane further states that for years, and at all times relevant to the Complaint, it has been common knowledge and universally understood, including by the State of Iowa and/or their agents, that AWP does not, and is not intended to, reflect an actual average of wholesale prices. To the extent the allegations in Paragraphs 303 refer to published reports by HHS and DOJ, the reports speak for themselves, and any characterizations thereof are denied.

304. Roxane denies the allegation in Paragraph 304.

305. Roxane admits that it has been investigated by DOJ and that it was asked to provide information to the House Committee on Energy and Commerce. Roxane lacks knowledge or information sufficient to form a belief as to the truth of the remaining



allegations in Paragraph 305, and therefore denies these allegations. Roxane specifically denies that it engaged in any “wrongful conduct.”

306. Roxane denies the allegations in Paragraph 306, except admits that it has been sued along with other defendants by the States of Alabama, Alaska, Hawaii, Idaho, Illinois, Kentucky, Massachusetts, Mississippi, Missouri, Ohio, Pennsylvania, South Carolina, Texas, Wisconsin, the City of New York and 42 New York Counties. Roxane specifically denies that it engaged in “wrongful conduct.”

307. Roxane denies the allegations in Paragraph 307.

308. Roxane lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 308, and therefore denies these allegations. Roxane further states that for years, and all times relevant to the Complaint, it has been common knowledge and universally understood, including by the State of Iowa and/or their agents, that AWP does not, and is not intended to, reflect an actual average of wholesale prices.

309. Roxane admits that Illinois alleges that in 2000, Roxane and its affiliates published an AWP for subject drug Furosemide 20 mg tablets of \$36.05. Roxane denies the remaining allegations in Paragraph 309 and further denies the truth of and characterizations in Illinois’ allegations.

310. Roxane lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 310, and therefore denies these allegations. Roxane further states that for years, and all times relevant to the Complaint, it has been

common knowledge and universally understood, including by the State of Iowa and/or their agents, that AWP does not, and is not intended to, reflect an actual average of wholesale prices.

Paragraphs 311 through 312. Roxane lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 311-312 and therefore denies these allegations and the exhibit referenced therein. Roxane specifically denies that these prices were “false and inflated” or that these prices were “fraudulent”.

313. Roxane denies the allegations in Paragraph 313.

314. Roxane denies the allegations in Paragraph 314.

315. Roxane lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 315, and therefore denies these allegations.

316. Roxane lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 316, and therefore denies these allegations and the exhibit referenced therein. Roxane specifically denies that these prices were “fraudulent.”

317. Roxane admits that it has been asked to supply information to the House Committee on Energy and Commerce regarding its pricing. Roxane denies the remaining allegations in Paragraph 317.

318. Roxane denies the allegations in Paragraph 318 as they pertain to Roxane, but admits that BIPI has been asked to supply information to the Senate Finance

Committee. Roxane lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 318, and therefore denies these allegations.

Paragraphs 319 through 613. The allegations in Paragraphs 319-613 are directed to other Defendants and require no response from Roxane. To the extent Paragraph 585 references Roxane, the allegations in that paragraph are denied. To the extent a response is deemed to be required to the remaining paragraphs, Roxane lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 263-613, and therefore denies these allegations.

Paragraphs 614 through 616. To the extent the allegations in Paragraphs 614-616 are directed at Roxane, Roxane denies them, except Roxane lacks knowledge or information sufficient to form a belief as to the truth of the allegation that Iowa's Medicaid program "spent over \$1.6 billion for defendants' drugs in state and federal dollars from 1992 through 2005 alone." Roxane specifically denies that it was involved in any "false price reporting scheme" or "misconduct," or that it has been "unjustly enriched." To the extent the allegations in Paragraphs 614-616 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

Paragraphs 617 through 632. To the extent the allegations in Paragraphs 617-632 are directed at Roxane, Roxane denies them. Roxane further states that for years, and at all times relevant to the Complaint, it has been common knowledge and universally understood, including by the State and/or its agents, that AWP does not, and is not

intended to, reflect an actual average of wholesale prices. To the extent the allegations in Paragraphs 617-632 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations. To the extent the allegations in Paragraph 630 refer to The Pink Sheet, that document speaks for itself, and any characterizations thereof are denied.

## **COUNT I**

### **VIOLATION OF FEDERAL MEDICAID STATUTE, 42 U.S.C. 1396r-8 (FAILURE TO COMPLY WITH FEDERAL MEDICAID REBATE PROVISION)**

633. In response to Paragraph 633, Roxane repeats and incorporates as if fully set forth herein each and every response to the allegations in Paragraphs 1 through 632.

Paragraphs 634 through 642. To the extent the allegations in Paragraphs 634-642 are directed at Roxane, Roxane states that the Court has dismissed the claim to which these allegations relate. To the extent that a response is still required, Roxane denies the allegations as to itself. To the extent the allegations in Paragraphs 634-642 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

## **COUNT II**

### **BREACH OF CONTRACT**

643. In response to Paragraph 643, Roxane repeats and incorporates as if fully set forth herein each and every response to the allegations in Paragraphs 1 through 642.

Paragraphs 644 through 651. To the extent the allegations in Paragraphs 644-651 are directed at Roxane, Roxane states that the Court has dismissed the claim to which

these allegations relate. To the extent that a response is still required, Roxane denies the allegations as to itself. To the extent the allegations in Paragraphs 644-651 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

### **COUNT III**

#### **IOWA CONSUMER FRAUD ACT (Iowa Code § 714.16)**

652. In response to Paragraph 652, Roxane repeats and incorporates as if fully set forth herein each and every response to the allegations in Paragraphs 1 through 651.

653. To the extent the allegations in Paragraph 653 and the exhibits referenced therein are directed at Roxane, Roxane denies them. To the extent the allegations in Paragraph 653 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations. To the extent the allegations in Paragraph 653 refers to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

Paragraphs 654 through 657. To the extent the allegations in Paragraphs 654-657 and the sub-parts thereto are directed at Roxane, Roxane denies them. To the extent the allegations in Paragraphs 654-657 and the sub-parts thereto are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations. To the extent the allegations in Paragraphs 654-657 and the sub-parts thereto refer to statutes, those sources speak for themselves, and any characterizations thereof are denied. To the extent the allegations in

Paragraphs 654-657 and the sub-parts thereto contain legal conclusions, no response is required.

#### **COUNT IV**

##### **FRAUD**

658. In response to Paragraph 658, Roxane repeats and incorporates as if fully set forth herein each and every response to the allegations in Paragraphs 1 through 657.

Paragraphs 659 through 662. To the extent the allegations in Paragraphs 659-662 and the exhibits referenced therein are directed at Roxane, Roxane denies them. To the extent the allegations in Paragraphs 659-662 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations. To the extent the allegations in Paragraphs 659-662 refer to Iowa law, those sources speak for themselves, and any characterizations thereof are denied. To the extent the allegations in Paragraphs 659-662 contain legal conclusions, no response is required.

#### **COUNT VIII**

##### **UNJUST ENRICHMENT**

663. In response to Paragraph 663, Roxane repeats and incorporates as if fully set forth herein each and every response to the allegations in Paragraphs 1 through 662.

Paragraphs 664 through 666. To the extent the allegations in Paragraphs 664-666 are directed at Roxane, Roxane denies them. To the extent the allegations in Paragraphs 664-666 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these

allegations. To the extent the allegations in Paragraphs 664-666 contain legal conclusions, no response is required.

Paragraphs 667 through 675. Roxane denies that the State is entitled to a judgment or any other relief as requested in the unnumbered “WHEREFORE” paragraph and Paragraphs 667-675 of the Complaint.

**WHEREFORE**, Roxane demands judgment dismissing the Complaint with prejudice, and awarding reasonable expenses and costs incurred herein, and for such further relief as the Court deems just and proper.

#### **AFFIRMATIVE DEFENSES**

Roxane reasserts and incorporates herein by reference the assertions of paragraphs 1 through 675 hereof.

##### **First Affirmative Defense**

Plaintiff fails to state a claim against Roxane upon which relief may be granted.

##### **Second Affirmative Defense**

Plaintiff’s claims are barred, in whole or in part, because it did not rely on any alleged misrepresentations or fraud by Roxane. Plaintiff knew that providers could obtain Roxane drugs at prices below AWP prior to the relevant time period stated in the Complaint.

##### **Third Affirmative Defense**

Plaintiff’s claims are barred, in whole or in part, by the political question and separation of powers doctrines.

**Fourth Affirmative Defense**

Plaintiff's claims are barred, in whole or in part, by the filed rate doctrine.

**Fifth Affirmative Defense**

Plaintiff's claims are barred, in whole or in part, by the state action doctrine.

**Sixth Affirmative Defense**

To the extent Plaintiff obtains recovery in any other case predicated on the same factual allegations, Plaintiff is barred from seeking recovery against Roxane based on the Complaint pursuant to the doctrines of res judicata and collateral estoppel, and the prohibition on double recovery for the same injury.

**Seventh Affirmative Defense**

Plaintiff's claims are barred, in whole or in part, by the Noerr-Pennington doctrine to the extent that such claims are premised, in whole or in part, on alleged statements or conduct by Roxane in judicial, legislative, or administrative proceedings of any kind or at any level of government.

**Eighth Affirmative Defense**

Plaintiff's claims are barred, in whole or in part, to the extent that Plaintiff has released, settled, entered into an accord and satisfaction or otherwise compromised Plaintiff's claims.

**Ninth Affirmative Defense**

Plaintiff's state law claims are preempted, in whole or in part, by federal law, including without limitation the Federal Employment Retirement Income and Security Act of 1974, the Federal Medicare Act, the Federal Medicaid Act, and the Prescription



Drug, Improvement and Modernization Act of 2003, including all amendments to the same and all regulations promulgated thereunder.

**Tenth Affirmative Defense**

Plaintiff's claims against Roxane are barred, in whole or in part, by the applicable statutes of limitations and repose, and by the doctrines of laches, estoppel, and waiver.

**Eleventh Affirmative Defense**

Plaintiff fails to state with particularity facts to support claims of fraudulent conduct, fraudulent concealment and the multi-source allegations against Roxane contained in the Complaint.

**Twelfth Affirmative Defense**

Any and all actions taken by Roxane with respect to any of the matters alleged in the Complaint were taken in good faith and in accordance with established industry practice.

**Thirteenth Affirmative Defense**

Roxane's statements or actions were not the proximate cause or cause in fact of any injury to or alleged loss by Plaintiff.

**Fourteenth Affirmative Defense**

Plaintiff's claims are barred, in whole or in part, because Plaintiff is not a consumer within the meaning of the Iowa Consumer Fraud Act.

**Fifteenth Affirmative Defense**

Plaintiff's claims are barred, in whole or in part, because Plaintiff is not a person within the meaning of the Iowa Consumer Fraud Act.

**Sixteenth Affirmative Defense**

Some or all of Plaintiff's claims against Roxane arise from Plaintiff's failure to follow its federal and state statutory and regulatory obligation to set reimbursement rates at Estimated Acquisition Cost.

**Seventeenth Affirmative Defense**

Roxane denies that Plaintiff has a valid consumer protection claim against Roxane under the Iowa Consumer Fraud Act. However, if such claim is found to exist, Roxane pleads all available defenses under the Act.

**Eighteenth Affirmative Defense**

To the extent that Plaintiff attempts to seek equitable relief against Roxane, Plaintiff is not entitled to such relief because Plaintiff has an adequate remedy at law.

**Nineteenth Affirmative Defense**

Plaintiff's claims are barred, in whole or in part, because Plaintiff would be unjustly enriched if allowed to recover any portion of the damages alleged in the Complaint.

**Twentieth Affirmative Defense**

Plaintiff's claims are barred, in whole or in part, by the doctrine of consent and/or ratification to the extent that Plaintiff has received and paid for medicines manufactured, marketed and sold by Roxane after the filing of the Complaint.

**Twenty-First Affirmative Defense**

Plaintiff's claims are barred, in whole or in part, because the damages alleged are speculative and remote and because of the impossibility of ascertaining and allocating those alleged damages.

**Twenty-Second Affirmative Defense**

Plaintiff's claims against Roxane are barred, in whole or in part, due to their failure to join indispensable parties.

**Twenty-Third Affirmative Defense**

Plaintiff's claims against Roxane are barred, in whole or in part, because Plaintiff has not suffered damages as a result of the matters alleged in the Complaint.

**Twenty-Fourth Affirmative Defense**

Plaintiff's claims are barred, in whole or in part, (1) because Plaintiff failed to mitigate damages, and that failure to mitigate damages should proportionately reduce the recovery of such persons and the allocation of any fault, if any exists, attributable to Roxane; (2) because Plaintiff would be unjustly enriched if allowed to recover any portion of the damages alleged in the Complaint; and (3) because damages are speculative and remote and because of the impossibility of ascertaining and allocating alleged damages.

**Twenty-Fifth Affirmative Defense**

Roxane is entitled to a set-off, should any damages be awarded against it, for the entire amount of all damages or settlement amounts recovered by Plaintiff, with respect to the same alleged injuries.

**Twenty-Sixth Affirmative Defense**

Plaintiff's claims against Roxane are barred, in whole or in part, by the First Amendment to the United States Constitution and the analogous provisions of the Iowa Constitution.

**Twenty-Seventh Affirmative Defense**

Plaintiff's claims against Roxane are preempted by the Commerce Clause and/or the dormant Commerce Clause of the United States Constitution.

**Twenty-Eighth Affirmative Defense**

Plaintiff's claims against Roxane are barred, in whole or in part, because they violate Roxane's rights under the Due Process and Ex Post Facto clauses of the United States Constitution, as well as the Iowa Constitution, insofar as Plaintiff seeks to impose liability retroactively for conduct that was not actionable at the time it occurred.

**Twenty-Ninth Affirmative Defense**

Plaintiff's claims against Roxane are barred because Plaintiff and/or its agents knew and were aware that AWP was not an actual average of wholesale prices or the actual acquisition cost of pharmaceuticals. Legal and equitable principles preclude this action for damages and injunctive relief.

**Thirtieth Affirmative Defense**

The claims alleged herein, based on the facts alleged, are barred in whole or in part by Plaintiff's own negligence or gross negligence and the doctrines of comparative and/or contributory negligence. Among other things, the claims disregard Iowa's obligations under federal law.

**Thirty-First Affirmative Defense**

Plaintiff's prayers for relief in the form of restitution are barred, in whole or in part, because Roxane did not retain any money belonging to Plaintiff as a result of any alleged overpayments.

**Thirty-Second Affirmative Defense**

Plaintiff has failed to plead with particularity allegations of fraud by Roxane contained in the Complaint.

**Thirty-Third Affirmative Defense**

Plaintiff's claims for fraud and fraudulent concealment are barred because the Plaintiff cannot predicate a claim for fraud on reliance by a third party.

**Thirty-Fourth Affirmative Defense**

Plaintiff's claims against Roxane are barred because Plaintiff lacks standing or capacity to bring the some or all of the claims asserted against Roxane under Iowa law.

**Thirty-Fifth Affirmative Defense**

Plaintiff's claims against Roxane are barred in whole or in part by the doctrine of voluntary payment.

**Thirty-Sixth Affirmative Defense**

Plaintiff's claims against Roxane for injunctive relief were mooted by the passage of the 2003 Medicare reform legislation.

**Thirty-Seventh Affirmative Defense**

Plaintiff's claims against Roxane for unjust enrichment are barred because the Complaint does not allege that Defendants received any payment or property from the Plaintiff.

**Thirty-Eighth Affirmative Defense**

Plaintiff's claims against Roxane for injunctive relief against Roxane are barred by the doctrines of in pari delicto and/or unclean hands.

**Thirty-Ninth Affirmative Defense**

Plaintiff's claims against Roxane are misjoined with Plaintiff's claims against other Defendants and must be severed.

**Fortieth Affirmative Defense**

Any damages recovered by the Plaintiff must be limited by any applicable statutory ceiling on recoverable damages.

**Forty-First Affirmative Defense**

To the extent punitive damages are sought, Plaintiff's punitive damages claims against Roxane (1) have no basis in law or fact; (2) are not recoverable because the allegations of the Complaint are legally insufficient to support a claim for punitive damages against Roxane; (3) cannot be sustained because the laws regarding the standards for determining liability for, and the amount of, punitive damages fail to give Roxane prior notice of the conduct for which punitive damages may be imposed and the severity of the penalty that may be imposed and are void for vagueness in violation of Roxane's due process rights guaranteed by the Fifth and the Fourteenth Amendments to

the United States Constitution; (4) cannot be sustained because any award of punitive damages exceeding the limits authorized by the laws or other comparable laws would violate Roxane's due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and be improper under the Iowa Constitution and Iowa common law.

**Forty-Second Affirmative Defense**

Plaintiff fails to allege facts or a cause of action against Roxane sufficient to support a claim for prejudgment interest or any other relief.

**Forty-Third Affirmative Defense**

Plaintiff has not suffered, and will not suffer, any injuries to a legally protected or cognizable interest by reason of the conduct of Roxane as alleged in the Complaint.

**Forty-Fourth Affirmative Defense**

Plaintiff's claims against Roxane are barred because Roxane has complied with all applicable regulations of the federal and state governments.

**Forty-Fifth Affirmative Defense**

Plaintiff's claims against Roxane are barred, in whole or in part, because any injuries sustained by Plaintiff were the result of intervening or superseding conduct of third parties.

**Forty-Sixth Affirmative Defense**

Plaintiff's claims against Roxane are barred, in whole or in part, because Roxane did not make any false statements to the Plaintiff. As to any statement asserted against Roxane that Plaintiff alleges to be false or misleading, Roxane had no reasonable grounds

to believe, and did not believe at the time such a statement was made, that the statement was false or misleading.

**Forty-Seventh Affirmative Defense**

Plaintiff fails to allege facts or a cause of action sufficient to support a claim against Roxane for compensatory damages, attorneys' fees, enhanced damages, treble damages and/or legal fees or costs.

**Forty-Eighth Affirmative Defense**

Roxane adopts by reference any additional applicable defense pled by any other Defendant not otherwise pled herein.

**Forty-Ninth Affirmative Defense**

Roxane hereby gives notice that it intends to rely upon any other and additional defense that is now or may become available or appear during, or as a result of the discovery proceedings in this action and hereby reserve its right to amend its Answer to assert such defense.



Respectfully submitted,

Dated: September 18, 2008

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**CERTIFICATE OF SERVICE**

I certify that a true and correct copy of the ANSWER AND AFFIRMATIVE DEFENSES OF BOEHRINGER INGELHEIM ROXANE, INC. TO THE STATE OF IOWA'S COMPLAINT was delivered to all counsel of record by sending a copy to LexisNexis File and Serve, on September 18, 2008, for posting and notification to all parties.

September 18, 2008

/s/ Lauren O. Casazza  
Lauren O. Casazza